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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,540	09/27/2000	Timothy W. King	121117-1000	6703

7590

12/17/2003

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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/17/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,540

Applicant(s)

KING ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time, and the Amendment B, both received by the Office September 22, 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 13-18, and 23-36 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,407, 609 to Tice *et al.*.

Tice *et al.* teach a method of encapsulating an agent. Tice *et al.* teach that a suitable wall forming material, such as a polymer, is first dissolved or otherwise dispersed in a solvent (c 3, l 50-52). The liquid or solid agent to be encapsulated is then dispersed or dissolved in the solvent containing the dissolved wall forming material (c 4, l 30-32). This mixture is then added to a continuous process medium to form microdroplets (c 5, l 50-52). The process medium is then mechanically agitated with devices such as homogenizers, propellers or the like (c 6, l 9-12). Once the emulsion is formed, the process medium is transferred to an extraction medium so that the solvent can be removed from the microdroplets (c 6, l 23-27). Lastly, the microcapsules or microspheres are collected by centrifugation, filtration or the like (c 6, l 42-46). Tice *et al.* teach that the active can be selected from a large group of possible therapeutic agents, including

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peptides and proteins, such as LHRH, growth hormone, and others (c 4, l 65-66). Tice *et al.* teach that the solvent can be methylene chloride, chloroform, and others (c 3, l 53-63). Tice *et al.* teach that polyvinyl alcohol can be used as the processing medium (c 5, l 60).

These teachings anticipate the above listed claims.

Response to Arguments

Applicant's arguments filed September 22, 2003 have been fully considered but they are not persuasive. Applicants argue that Tice *et al.* does not anticipate Applicants' claims because, although Tice *et al.* does teach a method of microencapsulating an agent, the method disclosed is different than that of Applicant. More specifically, Applicants argue that Tice *et al.* teach that microdroplets are formed after the agent is added to the wall material/ excipient solution, and the agent/ wall material- excipient/ solvent mixture dispersion is added to a continuous process medium. Applicants state that this differs from their claimed process because their microspheres are produced by extracting the organic solvent from the emulsion. The examiner does not find these arguments to be persuasive. First, Applicant using comprising language in the claims, which therefore does not exclude additional steps from being present in the method. Therefore, there is nothing in the claim which prevents adding the mixture to a continuous medium to form microdroplets. Additionally, as discussed by Applicant, Tice *et al.* are referring to the formation of microdroplets, NOT microspheres. Therefore, looking into the Tice *et al.* reference, it is clear that the microspheres are formed through extraction, in the same manner as Applicant. For these reasons, Applicants' arguments regarding this rejection are found to be unpersuasive, and the rejection is therefore maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tice *et al.*, in view of US Patent 5,622,657 to Takada *et al.*.

Tice *et al.* are discussed above as teaching Applicant's claimed method for forming microspheres. Tice *et al.* do not teach that the bioactive substance is stabilized with a carrier protein, such as albumin.

Takada *et al.* disclose a microparticles preparation comprising microparticles of a polymer which contain a drug and are coated with a film agent. Takada *et al.* are relied upon for the teaching that albumin, as well as gelatin, are known in microparticle formulations as a drug stabilizer. Takada *et al.* teach that during the production of the microparticles, stabilizers, such as albumin, can be added to stabilize the drug.

One of ordinary skill in the art would have been motivated to use a stabilizer, such as albumin, in a microparticle formulation to stabilize the active agent. The motivation lies in the teachings of Takada *et al.*, where it discloses that albumin is known in microparticle formulation to stabilize active agents. The expected result would be a successful, stabilized microparticle formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants' arguments filed September 22, 2003 have been fully considered but they are not persuasive. Applicant argues that there is no teaching within Tice *et al.* to stabilize the bioactive substance using albumin. This argument is found unpersuasive. The examiner clearly stated this in her rejection, and this is the entire reason an obviousness rejection, rather than an anticipation rejection, was used.

Applicants further argue that the secondary reference teaches adding albumin after the microspheres are formed. However, the examiner respectfully points out that claims 8 and 9, discussing the addition of a stabilizer, state nothing about when the stabilizer should be added. Therefore, there is nothing in the instant claims which prevents the addition of a stabilizer protein, such as albumin, after the microsphere formation. Therefore, Applicants' arguments are found unpersuasive, and the above rejection is maintained.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tice *et al.* in view of Baker *et al.*.

Tice *et al.* are discussed above as teaching Applicant's claimed method for forming microspheres. Tice *et al.* do not teach that the polymeric substance is a combination of PLGA and PEG.

Baker *et al.* teach a method for distributing a therapeutic agent in encapsulated form. Baker is relied upon for teaching that both PLGA and PEG are known in the art to as polymeric materials suitable for forming microparticles (c 5, l 46-50).

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One of ordinary skill in the art would have been motivated to use any well known wall forming material in a method to produce microparticles. The motivation lies in the teachings of Baker, which shows that both polyethylene glycol and PLGA are known encapsulating materials. The expected result would be a successful microparticle formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' arguments regarding this rejection appear to restate the arguments regarding the anticipation rejection. These arguments have been previously addressed. Further, Applicant argues that there is no motivation to combine the references. The examiner respectfully disagrees, for the reasons stated in the rejection itself. Therefore, this rejection is also maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
December 15, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNICAL CENTER 1600